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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,317	08/21/2006	**Christof Westenfelder**	10402-26	6531

7590 11/19/2010

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
11/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,317	WESTENFELDER, CHRISTOF	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-18,49-52 and 60* is/are pending in the application.

4a) Of the above claim(s) *4 and 11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-10,49-52 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/09, 6/14/10, and 8/26/10* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response received on 6/14/10 has been entered. Claims 3, 5, 19-48, and 53-59 are now canceled, and new claim 60 has been added. Claims 1-2, 4, 6-18, 49-52, and 60 are currently pending in the instant application. In view of applicant's amendment to claim 2, previously withdrawn from prosecution as being drawn to a non-elected species, claim 2 is rejoined with the claims currently under examination.

In regards to withdrawn, currently amended claims 4 and 18, it is noted that while these claims have been amended such that they recite the method of claim 1 further comprising either the administration of hemangioblasts (claim 4), or the administration of a stimulant of stem cell mobilization (claim 18), these claims remain withdrawn from prosecution for the following reasons. The applicant elected the species of "mesenchymal stem cells" as the species of cells to be examined. Based on applicant's argument in their response to the restriction/election requirement, the examiner further agreed to examine the combination of mesenchymal stem cells and hematopoietic stem cells, see the office action mailed on 12/14/09. The applicant has amended claim 4 and 18 such that they recite the administration of a combination of mesenchymal stem cells and hemangioblasts, or mesenchymal stem cells and a stimulant of stem cell mobilization, embodiments not present in the claims originally subject to restriction. Hemangioblasts or a stimulant of stem cell mobilization are not equivalent to hematopoietic stem cells. Instead, these are patentably distinct cells or molecules that differ materially in structure and function from hematopoietic stem cells. Since applicant has received an action on the merits for the originally presented invention, the administration of mesenchymal stem cells and

hematopoietic stem cells, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 4 and 18 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Further, claims 11-17 also remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Since no generic or linking claims has been found allowable, applicant's request for rejoinder is denied. The applicant is reminded that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-2, 6-10, 49-52, and 60 are therefore currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 12/31/09, 6/14/10, and 8/26/10 are in compliance with 37 CFR 1.97 and 1.98 and have been considered. Initialed and signed copies of the 1449s are attached to this action.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 5-10, and 45-53 under 35 U.S.C. 102(a) as being anticipated by Imai et al. (2002) Ped. Nephrol., Vol. 17, 790-794, is withdrawn over canceled claims 3, 5, 45-48, and 53, withdrawn over claims 51-52 in view of the amendments to these claims which now recite the administration of an active ingredient consists essentially of mesenchymal stem cells, and maintained over amended claims 1-2, 6-10, 49-50, and 60.

The applicant argues that the claims have been amended to recite "isolated mesenchymal stem cells" and that Imai et al. does not teach this limitation. The applicant further argues that Imai et al. does not anticipate the instant methods because the mouse model of kidney disease used in the experiments set forth in Imai et al. are not "in need of treatment" since the kidney condition can resolve without therapy, and that Imai et al. does not show that the mesenchymal stem cells treat the kidney disease because certain controls were missing from the experiments.

In response, it is not agreed that Imai et al. does not teach "isolated mesenchymal stem cells. The term "isolated" has not been accorded any particular definition by the specification, and is generally understood to mean removed or separated from something else. It is further noted that an "isolated" cell is not equivalent to one which as been purified or enriched and the claim as written do not place any limitation on the purity of the isolated mesenchymal stem cells. Imai et al. teaches the isolation of bone marrow which comprise mesenchymal stem cells from various mammals. As such, Imai et al. teaches an isolated mesenchymal stem cell.

In regards to the limitation of administering the cells to a patient "in need thereof", applicant's argument that the rat model of kidney dysfunction used by Imai et al. does not qualify as a subject in need of treatment is not found persuasive since Imai et al. characterizes the anti-Thy-1 antibody mediated glomerulonephritis present in these rats as a well established self-

limiting disease, and Thy1 nephritis has clearly been developed and used in the art as a model of kidney dysfunction useful for testing potential therapeutics for kidney dysfunction and disease. Thus, regardless of whether the kidney dysfunction in these mice would resolve by itself over an extended period of time, the Thy1 nephritis animal model used by Imai et al. is art recognized as a model patient "in need" of treatment for kidney dysfunction.

Finally, it is disagreed that Imai et al. is not anticipatory because they did not report on data from a control in which rats that did not received bone marrow had a worse clinical outcome. Imai et al. teaches the administration of bone marrow comprising mesenchymal stem cells and hematopoietic stem cells to a rat model of kidney dysfunction. As such Imai et al., teaches the exact methods steps as claimed. Whether or not Imai et al. definitively demonstrated a treatment effect on the kidney dysfunction is irrelevant since it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff*, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); *In re Swinehart*, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Thus, for the reasons set forth above and of record, the rejection stands.

The rejection of claims 51-53 under 35 U.S.C. 102(b) as being anticipated by Fibbe et al. (2001) Ann. N.Y. Acad. Sci., Vol. 938, 9-17, is withdrawn in view of the cancellation of claim 53 and the amendments to claims 51-52 which are now limited to the administration of an active ingredient consisting of mesenchymal stem cells.

Applicant's amendments to the claims has necessitated the following new grounds of rejection of claims 51-52.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 51-52 are newly rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/13588 (2/24/03), hereafter referred to as Tabata et al. Tabata et al. was published in Japanese. A machine translation of this document has been provided with this action. The teachings of Tabata et al. set forth below are based on the machine translation.

Tabata et al. teaches to a composition comprising a collagen sponge scaffold containing purified mesenchymal stem cells, where the purified mesenchymal stem cells are the "active ingredient" (Tabata, see the last page of the translation, in particular, the discussion of Figure 2). Tabata et al. states that while the implantation of the sponge comprising mesenchymal stem cells into an injured kidney did not result in "rebirth of the glomerular organization", formation of renal tubules was observed (Tabata et al., last page of the translation, and Figure 2). Thus, by teaching all the limitations of claimed composition, Tabata et al. anticipates the instant invention as claimed.

Claims 51-52 are newly rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,486,359 (1999), hereafter referred to as Caplan et al.

Caplan et al. teaches a therapeutic composition comprising an isolated homogenous population of mesenchymal stem cells as the "active" ingredient, and a pharmaceutically acceptable carrier (Caplan et al., claims 1-11, and 32-36). While Caplan et al. does not disclose the intended use for the cell composition recited in the preamble of claim 51, i.e. an intended use of the cells for the treatment of a patient with a kidney dysfunction, it is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Caplan et al. teaches a composition identical to the composition as claimed. "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or *In re Best*, 195 USPQ 430, 433 (CCPA 1997). Further, the applicant is reminded that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). Thus, by teaching a composition identical in structure to the composition as claimed, Caplan et al. anticipates the instant invention.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the

USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633